Notice of Allowability	Application No.	Applicant(s)	
	10/559,407	KU, YUN-HEE	
	Examiner	Art Unit	
	GORDON J. STOCK JR	2877	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *after final amendments received 1/2/09 and 1/5/09*.

2. ☒ The allowed claim(s) is/are *1-10*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20090107* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☒ Other *PTOL-413A*.

DETAILED ACTION

1. The Amendments received on January 2, 2009 and January 5, 2009 have been entered into the record (the amendments are substantially identical with the exact same amendment to the claims and specification; however, they differ in regards to page 10 of Remarks (different Figure) and slightly different wording on page 15 of Remarks).

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Peter Kwon on January 7, 2009. Please see interview summary of PTOL-413 for details. **Claims 1 and 8** will be amended, and cancelled **claim 11** will be listed with proper identifier. Also there will be amendments to the specification to make the amendment to the specifications of amendment received on January 5, 2009 (and subsequently, January 2, 2009) as well as the amendment to the specification received on June 12, 2008 compliant.

The **amended claims with a complete listing of the claims** are as follows:

1. (Currently Amended) An instrument for measuring blood cell deformability comprising:

a disposable blood test kit (20) for directly containing blood sample,

a light emitting unit (10) disposed above said disposable blood test kit (20),

a measurement unit (30) for measuring the blood cell deformability,

said disposable blood test kit (20) comprises a blood sample pot (21) for containing the blood sample, a slit channel (22) for flowing the blood sample by a pressure difference, and a waste blood pot (23) for collecting the tested blood sample,

said measurement unit (30) comprises a differential pressure generator (33), which is connected to the disposable blood test kit (20) through a connecting tube and a valve (32) for generating the pressure difference between the blood sample pot (21) and waste blood pot (23), a pressure gauge (34) connected to the differential pressure generator (33) and the disposable blood test kit (20) for measuring the pressure difference, a means for projecting diffracted images of [[the]] blood cells, an image capturing unit (35) for capturing the diffracted images, a control unit (36) for calculating the blood cell deformability and variation of a shearing force according to [[the]] blood cell deformation on time based data received from the pressure gauge (34) and the image capturing unit (35), an output unit (37) for printing the calculated information on a sheet or displaying on an LCD screen, and a memory unit (38) for storing the calculated information and images,

wherein said control unit (36) further calculates a shearing stress (τ) as a function of time, which is calculated and stored by a computer analyses based on time data of pressure measurements, alternatively, said shearing stress (τ) is ~~can be~~ determined according to pre-calculated data of pressure without applying [[the]] instantly measured pressure data, and the diffracted images of the blood cells captured by the image-capturing unit (35) are analyzed by ellipse curve-fitting computer software to determine a length (L) and a width (W) of analyzed elliptic images, and calculates a Deformation Index (DI) for determining the blood cell deformability and the shearing stress (τ) as a function of time.

2. (Previously Presented) An instrument for measuring blood cell deformability as claimed in claim 1, wherein said differential pressure generator (33) is connected to the waste blood pot (23) of the disposable blood test kit (20) through a connecting tube and a valve (32) for generating vacuum pressure, negative pressure, at the waste blood pot (23), so that the blood sample flows toward the waste blood pot (23) through the slit channel (22).

3. (Previously Presented) An instrument for measuring blood cell deformability as claimed in claim 1, wherein said differential pressure generator (33-1) is connected to the blood sample pot (21) of the disposable blood test kit (20) through a connecting tube and a valve (32) for generating positive pressure at the blood sample pot (21), so that the blood sample flows toward the waste blood pot (23) through the slit channel (22).

4. (Original) An instrument for measuring blood cell deformability as claimed in claim 1, wherein said slit channel (22) is optically transparent and has a clearance with a rectangular shape.

5. (Previously Presented) An instrument for measuring blood cell deformability as claimed in claim 1, wherein said disposable blood test kit (20) is made of a transparent material, which is one of silicon, silica, quartz, glass, a polymer produced by a laser, an extruded polymer, or ceramics.

6. (Previously Presented) An instrument for measuring blood cell deformability as claimed in claim 1, further comprises a heat control device, which is a thermo-electric component, a temperature control block, a hot-cold water jacket, or a halogen-lamp for adjusting and maintaining constant testing temperature surrounding the disposable blood test kit.

7. (Previously Presented) An instrument for measuring blood cell deformability as claimed in claim 1, wherein said image capturing unit (35) enables capturing the diffracted images of the deformed blood cell projected on a screen.

8. (Currently Amended) An instrument for measuring blood cell deformability as claimed in claim 1, wherein said image capturing unit (35) enables directly capturing the diffracted images of the deformed blood cell by employing a CCD sensor array ~~without projecting on a screen~~.

9. (Previously Presented) An instrument for measuring blood cell deformability as claimed in claim 1, wherein said image capturing unit (35) can be adopted either a CCD sensor array, CCD camera, digital camera, web camera or video camera for capturing images.

10. (Original) An instrument for measuring blood cell deformability as claimed in claim 1, wherein said light emitting unit (10) is adopted as either a Laser Diode or Light Emitting Diode (LED).

11. (Cancelled)

The **Specification is amended** as follows:

Please replace the paragraph starting on line 6 of page 3 with the following amended paragraph:

An objective of the present invention is to provide an instrument for measuring blood cell deformability comprising a disposable blood test kit (20) for directly containing the blood sample, a light emitting unit (10) disposed above the disposable blood test kit (20), and a measurement unit (30) for measuring the blood cell deformability. The disposable blood test kit (20) comprises a tiny blood sample pot (21) for containing the blood sample, a slit channel (22) for flowing the blood sample by the pressure difference, and a tiny waste blood pot (23) for collecting the tested blood sample. The measurement unit (30) comprises: a differential pressure generator (33) connected to the disposable blood test kit (20) through a connecting tube and a valve (32) for generating the pressure difference between the tiny blood sample pot (21) and the tiny waste blood pot (23); a pressure gauge (34) connected to the differential pressure generator (33) and the disposable blood test kit (20) for measuring the pressure difference; a screen (31) for projecting the diffracted images of the blood cell; an image capturing unit (35) for capturing the diffracted images; a control unit (36) for calculating the blood cell deformability[[,]] with variation of the shearing force, which are determined through a computer analyses on time based data of the captured images and the pressure measurements ~~and deformation on time based on data received from the pressure gauge (34) and the image capturing unit (35)~~; an output unit (37) for printing the calculated information on the sheet or

displaying on an LCD screen; and a memory unit (38) for storing the calculated information and images.

Please replace the paragraph starting on line 1 of page 4 with the following amended paragraph:

Another objective of the present invention is to provide the differential pressure generator (33) connected to the tiny waste blood pot (23) of the disposable blood test kit (20) through a connecting tube and a valve (32) for generating vacuum pressure at the tiny waste blood pot (23), so that the blood sample flows toward the tiny waste blood pot (23) through the slit channel (22). The slit channel (22) is optically transparent and has a clearance with a rectangular shape. The disposable blood test kit (20) is made of a transparent material such as [[a]] silicon, silica, quartz, glass, a polymer produced by a laser, an extruded polymer or ceramics.

Please replace the paragraph starting on line 9 of page 4 with the following amended paragraph:

Still another objective of the present invention is to provide the differential pressure generator (33) connected to the tiny blood sample pot (21) of the disposable blood test kit (20) through a connecting tube and a valve (32) for generating positive pressure at the tiny blood sample pot (21), so that the blood sample flows toward the tiny waste blood pot (23) through the slit channel (22). The image-capturing unit (35) enables capturing the diffracted image of the deformed blood cell by projecting on the screen. Alternatively, the image-capturing unit (35) enables directly capturing the diffracted image of the deformed blood cell without projecting on

the screen. The image capturing unit (35) ~~could use~~ can be adopted a CCD sensor array, a CCD camera, a digital camera, a web camera, or a video camera for capturing the diffracted images. The light-emitting unit (10) is adopted either as a Laser Diode or Light Emitting Diode (LED).

Please add new paragraph following line 2 of page 6:

Fig. 10 is an alternative configuration of the instrument equipped with the image capturing unit (35), such as a CCD sensor array for directly capturing the diffracted images without screen of the present invention.

Please replace the paragraph starting on line 21 of page 6 with the following amended paragraph:

The measurement unit (30) comprises: a differential pressure generator (33) which is connected to the disposable blood test kit (20) through a connecting tube and valve (32) for generating the different pressures between the tiny blood sample pot (21) and tiny waste blood pot (23), so that the blood sample passes through the slit channel of the disposable blood sample test kit (20); a pressure gauge (34) connected to the differential pressure generator (33) and the disposable blood sample test kit (20) for sequentially indicating the differential pressure; ~~a screen (31) for projecting the diffracted images of the blood cell which is passed through the slit channel; an image capturing unit (35) for capturing the images; a control unit (36) for calculating the blood cell deformability , variation of the shearing force, and deformation on time based on the data received from the pressure gauge (34) and the image capturing unit (35)~~ a screen (31)

for projecting the diffracted images of the blood cells, which were generated by light diffracting of blood cells passing through the slit channel; an image capturing unit (35) for capturing the images; a control unit (36) for determining the blood cell deformability and the shearing force on time based data of the captured images and measured pressure through the computer image analysis; an output unit (37) for printing the calculated information on the sheet or displaying on an LCD screen; and a memory unit (38) for storing the calculated information and images.

Please replace the paragraph starting on line 11 of page 7 with the following amended paragraph:

The diluted blood sample is injected into the tiny blood sample pot (21) of the disposable blood test kit (20). When the blood sample penetrates through the slit channel and passes underneath the light emitting unit (10), the emitted light is diffracted through the deformed blood cell to project the images on the screen. The instrument of the present invention has equipped a Laser diffraction device and a driving pressure varying device to measure and analyze the blood cell deformability.

Please replace the paragraph starting on line 9 of page 8 with the following amended paragraph:

The measurement unit (30) comprises: a differential pressure generator (33) connected to the disposable blood test kit (20) via a connecting tube and valve (32) to generate a vacuum pressure at the tiny waste blood pot (23) for driving the blood sample through the slit tunnel of the disposable blood sample test kit (20); a pressure gauge (34) connected to the differential

pressure generator (33) and the disposable blood sample test kit (20) for continuously measuring the differential pressures; a screen (31) for projecting the diffracted images of the blood cells which [[is]] are passed through the slit channel; an image capturing unit (35) for capturing the images; a control unit (36) for calculating the blood cell deformability[[,]] with variation of the shearing force, ~~and deformation on time based on the data received from the pressure gauge (34) and the image capturing unit (35)~~ which are determined on time based data of the captured images and the pressure measurements by the computer analyses; an output unit (37) for printing the calculated information on the sheet or displaying on an LCD screen; and a memory unit (38) for storing the calculated information and images.

Please replace the paragraph starting on line 22 of page 8 with the following amended paragraph:

At this point, the image capturing unit (35) enables capturing the deformed blood cell diffraction image ~~by projecting~~ projected on the screen while the blood sample is passed under the light emitting unit through the slit channel (22). For capturing the images, the image capturing unit (35) can be adopted either a CCD camera, digital camera, web camera, or a video camera. Alternatively, the deformed blood cell diffraction image can be directly captured by the image-capturing unit (35) without projecting on the screen by adopting a CCD sensor array as the image capturing unit (35). The CCD sensor array is able to detect the light intensity of the diffracted images and determine the blood cell deformation from the detected light signal on the sensor array. Thus, the deformability can be determined from the diffracted light, which is directly projected on the CCD-sensor array without projecting screen.

Please replace the paragraph starting on line 13 of page 11 with the following amended paragraph:

On the other hand, the image capturing unit (35) captures the deformed blood cell image for analyzing the deformability of the blood cell in the ratio of length and breadth and for determining the Deformation Index (DI) through the image analysis computer programming. The images of the blood cell diffraction captured by the image-capturing unit (35) are analyzed by ellipse curve-fitting computer software to determine the length (L) and width (W) of the analyzed elliptic images, and calculating the Deformation Index (DI). The Deformation Index "DI = (L-W)/(L + W)" is defined as the ratio of the difference to the sum of the length and the width.

Please replace the paragraph starting on line 16 of page 12 with the following amended paragraph:

The Deformation Index (DI) represents the diffracted blood cell images in the ratio of length to breadth and defined in Equation 1 as follows:

Equation 1: DI = ~~(A-B)/(A+B)~~ (L-W)/(L + W), wherein DI represents Deformation Index, L is the length and W is the width.

Please replace the paragraph starting on line 19 of page 14 with the following amended paragraph:

The slit channel (22) having a rectangular shape of height H, width W, and length L is loaded with the operating pressures and fluid volume on both ends, and the shear rate could be calculated with the pre-calculated data of the volume variation from Equation 5 as follows:

Equation 5: $\gamma = (1/3)[6Q/(WH2)][2 + \{d(\ln Q)/ d(\ln \tau)\}]$

Please replace the paragraph starting on line 2 of page 15 with the following amended paragraph:

It is also possible to apply a different method to calculate the shear force instead of the ~~volume~~ direct measuring pressure. When the blood sample is prepared, the Buffer solution is dissolved to dilute five micro-liters of blood sample with the mixing rate of 100:1 or 200:1.

Please replace the paragraph starting on line 6 of page 15 with the following amended paragraph:

Because the volume of the blood sample is very small in the buffer solution, the effect of viscosity of the blood in the diluted blood sample may be ignored. Therefore, the viscosity of the diluted blood sample is considered the same as that of the buffer solution. Even though a different blood sample is diluted into the buffer solution, the viscosity of the diluted blood sample is negligibly changed.

Please replace the paragraph starting on line 19 of page 15 with the following amended paragraph:

As an implementing example, it is a special character of the present invention that the shear stress can be obtained by the pre-measured data or pre-calculated data of the differential pressure without detecting the instant pressure. It is also possible to plot the graph of the blood cell deformability with respect to the shear force as a function of the time based on the pre-calculated shear stress.

Allowable Subject Matter

3. **Claims 1-10** are allowed.

The following is an examiner's statement of reasons for allowance:

As to **claim 1**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in an instrument for measuring blood cell deformability 'wherein said control unit (36) further calculates a shearing stress (τ) as a function of time, which is calculated and stored by a computer analyses based on time data of pressure measurements, alternatively, said shearing stress (τ) is determined according to pre-calculated data of pressure without applying instantly measured pressure data, and the diffracted images of the blood cells captured by the image-capturing unit (35) are analyzed by ellipse curve-fitting computer software to determine a length (L) and a width (W) of analyzed elliptic images, and calculates a Deformation Index (DI) for determining the blood cell deformability and the shearing stress (τ) as a function of time,' in combination with the rest of the limitations of **claims 1-10.**

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

4. Applicant's arguments, see Remarks pages 8-15 filed January 5, 2009 (similar arguments found in Remarks pages 8-15 filed January 2, 2009) with respect to the previous rejections under 35 U.S.C. 112 first paragraph and second paragraph and objections to claims and specification (see previous action: 20081007) have been fully considered and are persuasive. Due to the persuasiveness of the arguments as well as to the amendment to the claims and specification the previous objections and rejections have been subsequently withdrawn.

Fax/Telephone Numbers

If the applicant wishes to send a fax dealing with either a proposed amendment or a discussion with a phone interview, then the fax should:

1) Contain either a statement "DRAFT" or "PROPOSED AMENDMENT" on the fax cover sheet; and

2) Should be unsigned by the attorney or agent.

This will ensure that it will not be entered into the case and will be forwarded to the examiner as quickly as possible.

Papers related to the application may be submitted to Group 2800 by Fax transmission. Papers should be faxed to Group 2800 via the PTO Fax machine located in Crystal Plaza 4. The form of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CP4 Fax Machine number is: **(571) 273-8300**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gordon J. Stock whose telephone number is (571) 272-2431. The examiner can normally be reached on Monday-Friday, 8:00 a.m. - 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley, Jr., can be reached at 571-272-2800 ext 77.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/G. J. S./

Examiner, Art Unit 2877

/Gregory J. Toatley, Jr./

Supervisory Patent Examiner, Art Unit 2877

January 16, 2009